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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/050,249	03/30/1998	HARUKI OKAMURA	OKAMURA=2B	6601

1444 7590 02/11/2004

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WASHINGTON, DC 20001-5303

EXAMINER
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JIANG, DONG

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 02/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/050,249

Applicant(s)

OKAMURA ET AL.

Examiner

Dong Jiang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 93-120 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 93-120 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

### **DETAILED OFFICE ACTION**

The request filed on 19 November 2003 for a Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 09/050,249 is acceptable, and a RCE has been established. An action on the RCE follows.

Applicant's amendment filed on 03 November 2003 is acknowledged and entered. Following the amendment, claims 93, 94, 103 and 120 are amended.

Currently claims 93-120 are pending and under consideration.

#### **Withdrawal of Objections and Rejections:**

The rejection of claims 95-97, 118 and 120 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn in view of applicant's amendment.

The enablement rejection of claims 93-96 and 98-118 under 35 U.S.C. 112, first paragraph, made in the last Office Action, paper No. 31, is withdrawn in view of applicant's amendment.

#### **New Matter Rejection:**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 93-96, 98-117 and 119 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The newly amended claim 93 recites the limitation "*a variant thereof which has the same antigenic fragment(s) as in (i)* to be used in obtaining said monoclonal antibody", which constitutes the new matter because they are not found in the original disclosure, and the specification provides no basis for such a limitation.

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At pages 10-11 of the response, the applicant argues that “has the same antigenic fragment(s) as in (i)” is implicitly supported by the specification even though it is not literally and explicitly disclosed, that for example, the specification discloses a monoclonal antibody specifically recognizes IGIF, and can be obtained by using the protein or its antigenic fragments, and that those of skill in the art would clearly understand that the claimed antibody *should* specifically recognize a variant of IGIF having the same antigenic fragments as in IGIF. This argument has been fully considered, but is not deemed persuasive because the specification merely teaches *one* sequence of IGIF, and no concept of a variant having the same antigenic fragment(s) as in IGIF is ever disclosed or described. As such, it would not be clear to those of skill in the art that a functional variant of the disclosed IGIF would necessarily possess the same antigenic fragments without explicit disclosure in the specification, and the original disclosure does not reasonably convey to one of ordinary skill in the art that applicant was in possession of the variant now claimed at the time the application was filed.

This is a new matter rejection.

**Objections and Rejections under 35 U.S.C. 112:**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 94, 98-117 and 119 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons set forth in the last Office Action, paper No. 31, mailed on 20 May 2003, at page 2, and for the reasons below.

Claim 94 remains indefinite for omitting essential elements. Applicants argument filed on 03 November 2003 has been fully considered, but are not deemed persuasive for reasons below.

The newly amended claim 94 completely eliminates the washing step. At page 9 of the response, the applicant argues that the hybridization conditions are of sufficiently high stringency that the wash is not considered an essential element, and that while a wash step is preferred only to remove labeled probe that is not hybridized, the wash conditions are irrelevant

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because the high stringency during hybridization would have already eliminated any significant non-specifically or loosely hybridized probe. This argument is not persuasive because the art has not established that a wash step is preferred only to remove labeled probe that is not hybridized even under "the high stringent hybridization conditions", such as those in the present invention, nor that the high stringency hybridization would guarantee 100% specific hybridization. In fact, the wash step is considered one of the most important steps of the hybridization, and it is the wash step that finally determines stringency.

The remaining claims remain rejected for depending from an indefinite claim.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 93-96 and 98-118 remain rejected under 35 U.S.C. 112, first paragraph, as lacking adequate written description for the reasons set forth in the previous Office Actions, paper Nos. 22, 24, 29 and 31.

Applicants have presented no argument towards the rejection to the broad genus of IL-18.

**Rejections Over Prior Art:**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 93-120 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Nakamura *et al.* (*Infect. Immun.* 61: 64-70, 1993), for the reasons set forth in the previous Office Actions, paper No. 22, 24, 29 and 31.

Applicants argument filed on 03 November 2003 has been fully considered, but are not deemed persuasive for reasons below.

At pages 12-13 of the response, the applicant argues that Nakamura's factor is a substance which is a mixture of more than one protein, that it is impossible for a skilled person to obtain monoclonal antibody specific to IGIF using the mixture and that homogeneous pure protein had been required in order to obtain monoclonal antibodies at that time the present invention was filed. This argument is not persuasive for the following reasons. First, Nakamura (*Infect. Immun.* 63: 3966-3972, 1995) confirms that IGIF in the serum sample (75 kDa, *Infect. Immun.* 61: 64-70, 1993) was proved to be the same IGIF as that found in the liver extract (19 kDa), and merely speculates that *it was considered* to be bound to another protein *or* to exist in an oligomeric form (page 3969, the second paragraph of the left column). Further, even if IGIF were bound to *another* protein, it would not be a limiting factor to prevent a skilled person to obtain monoclonal antibody to IGIF because Nakamura's factor is relatively pure, and the key step to obtain the monoclonal antibody is to isolate a single cell line (a hybridoma) producing a monoclonal antibody to IGIF, not that the protein has to be 100% homogenous. The technique to obtain such a cloned cell line had been well established and widely practiced at the time the present invention was filed.

**Conclusion:**

No claim is allowable.

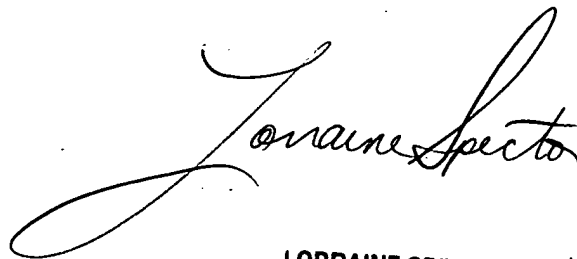
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**Advisory Information:**

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

A handwritten signature in cursive script, reading "Lorraine Spector". The signature is written in black ink and is positioned above a typed nameplate.

**LORRAINE SPECTOR  
PRIMARY EXAMINER**

Dong Jiang, Ph.D.  
Patent Examiner  
AU1646  
2/3/04